



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Patent Docket P1085R4-1A

In re Application of Vanessa Hsei et al. Serial No.: 09/234,182 Filed: 20 January 1999 For: ANTIBODY FRAGMENT- POLYMER CONJUGATES AND HUMANIZED ANTI-IL-8 MONOCLONAL ANTIBODIES	Group Art Unit: 1643 Examiner: Not Yet Assigned  <b>CERTIFICATE OF MAILING</b> I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Assistant Commissioner of Patents, Washington, D.C. 20231 on May 26, 1999 <i>(Signature)</i> Yvonne E. Carter
--	---

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner of Patents  
Washington, D.C. 20231

Sir:

Applicants submit herewith patents, publications or other information (attached hereto and listed on the attached Form PTO-1449) of which they are aware, which they believe may be material to the examination of this application and in respect of which there may be a duty to disclose in accordance with 37 CFR §1.56.

This application is related to co-pending application U.S. Serial No. 08/804,444 filed February 21, 1997, co-pending application U.S. Serial No. 09/012,116 filed January 22, 1998, co-pending application U.S. Serial No. 09/026,985 filed February 20, 1998, co-pending application U.S. Serial No. 09/027,449 filed February 20, 1998, co-pending application U.S. Serial No. 09/121,952 filed July 24, 1998, co-pending application U.S. Serial No. 09/122,513 filed July 24, 1998, co-pending application U.S. Serial No. 09/234,340 filed January 20, 1999 and co-pending application U.S. Serial No. 09/254,909 filed January 19, 1999.

On or about May 21-25, 1995, a poster entitled "Site-Specific Coupling of Monomethoxypoly(ethylene glycol) to a Single-Sulfhydryl Humanized Fab" naming as authors Gerardo Zapata, Dorothy Bates, Monika Schoenhoff, Jim Deveney, Steve Frie, Brad Snedecor, Paul Carter and Steven M. Chamow was presented at a poster session of the American Society for Biochemistry and

Molecular Biology FASEB Meeting held on May 21-25, 1995. All of the information that was disclosed in the aforementioned poster is contained in a 27 page reproduction of the poster enclosed with the present Information Disclosure Statement.

On February 23, 1997, a poster entitled "Humanization of Murine 6G425: An Anti-IL-8 Monoclonal Antibody which Blocks Binding of IL-8 to Human Neutrophils" naming as authors Tania N. Gonzalez, Steven R. Leong, Rhona Kabakoff, Caroline Hebert and Leonard G. Presta was presented at a poster session of the 1996 Keystone Symposia on Exploring and Exploiting Antibody and Ig Superfamily Combining Sites held on February 23-24, 1996. All of the information that was disclosed in the aforementioned poster is contained in a 21 page reproduction of the poster enclosed with the present Information Disclosure Statement.

On or about July 25-29, 1998, an abstract entitled "Tailoring Antibody Fragments with PEGylation without Loss in Biological Activity" naming as authors Iphigenia L. Koumenis, Gerardo Zapata, Steve Leong, Vanessa Hsei and Zahra Shahrokh was presented at The Protein Society 12th Symposium held on July 25-29, 1998. The abstract was published in Protein Science, 7(Suppl. 1):73 (July, 1998), Abstract #109-M, a copy of which is enclosed with the present Information Disclosure Statement.

This Information Disclosure Statement:

- (a) ☐ accompanies the new patent application submitted herewith. 37 CFR §1.97(a).
- (b) ☐ is filed within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 CFR§1.491.
- (c) ☒ as far as is known to the undersigned, is filed before the mailing date of a first Office action on the merits. Should any fee be due, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$240.00 to cover the cost of this Information Disclosure Statement. Any deficiency or overpayment should be charged or credited to this deposit account.
- (d) ☐ is filed after the first Office Action and more than three months after the application's filing date or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever occurs first, and is accompanied by either the fee (\$240) set forth in 37 CFR §1.17(p) **or** a statement as specified in 37 CFR §1.97(e), as checked below. Should any fee be due, the U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$240.00 to cover the cost of this Information Disclosure Statement. Any deficiency or overpayment should be charged or credited to this deposit account. **A duplicate of this sheet is enclosed.**

- (e) ☐ is filed after the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$130) set forth in 37 CFR §1.17(i) **and** a statement as specified in 37 CFR §1.97(e), as checked below. **This document is to be considered as a petition requesting consideration of the information disclosure statement.** The U.S. Patent and Trademark Office is hereby authorized to charge Deposit Account No. 07-0630 in the amount of \$130.00 to cover the cost of this Information Disclosure Statement. Any deficiency or overpayment should be charged or credited to this deposit account. **A duplicate of this sheet is enclosed.**

[If either of boxes (d) or (e) is checked above, the following statement under 37 CFR §1.97(e) may need to be completed.] The undersigned states that:

- ☐ Each item of information contained in the information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application and, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this information disclosure statement.

A list of the patent(s) or publication(s) is set forth on the attached Form PTO-1449 (Modified).

A copy of the items on PTO-1449 is supplied herewith:

☒ each ☐ none ☐ only those listed below:

Those patent(s) or publication(s) which are marked with an asterisk (\*) in the attached PTO-1449 form are not supplied because they were previously cited by or submitted to the Office in a prior application Serial No. , filed and relied upon in this application for an earlier filing date under 35 USC §120.

A concise explanation of relevance of the items listed on PTO-1449 is:

- ☐ not given
- ☐ given for each listed item
- ☒ given for only non-English language listed item(s) [Required]

WO 96/02576 disclosed the humanization of murine anti-human IL-8 monoclonal antibody WS-4, which disclosure is apparent from Tables 2, 3 and 4 on pages 11, 13 and 14 of corresponding EP 770,628 (English translation). A copy of EP 770,628 is submitted herewith.

[] in the form of an English language copy of a Search Report from a foreign patent office, issued in a counterpart application, which refers to the relevant portions of the references.

The Examiner is reminded that a "concise explanation of the relevance" of the submitted prior art "may be nothing more than identification of the particular figure or paragraph of the patent or publication which has some relation to the claimed invention," MPEP §609.


While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR §1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR §1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR §1.56(a) exists. It is submitted that the Information Disclosure Statement is in compliance with 37 CFR §1.98 and MPEP §609 and the Examiner is respectfully requested to consider the listed references.

Respectfully submitted,

GENENTECH, INC.

By:

  
Richard B. Love

Reg. No. 34,639

Date: May 24, 1999

1 DNA Way  
So. San Francisco, CA 94080-4990  
Phone: (650) 225-5530  
Fax: (650) 952-9881